

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
(609) 989-2040

CHAMBERS OF
TONIANNE J. BONGIOVANNI
UNITED STATES MAGISTRATE JUDGE

U.S. COURTHOUSE
402 E. STATE STREET, RM 6052
TRENTON, NJ 08608

December 2, 2011

LETTER ORDER

Re: SPD Swiss Precision Diagnostics GmbH v. Church & Dwight Co., Inc.
Civil Action No. 09-1802 (FLW)

Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics GmbH
Civil Action No. 10-276 (FLW)

Dear Counsel:

As you are aware, pending before the Court are several discovery issues, one of which involves SPD Swiss Precision Diagnostics GmbH's ("SPD") request that the Court require Church & Dwight Co., Inc. ("Church & Dwight") to produce documents related to Church & Dwight's February 2010 510(k) application in which Church & Dwight sought FDA approval of its proposed "over 99% accurate" statement for its First Response Early Result pregnancy test.¹ The Court addresses this issue herein.

On November 29, 2010, the Court addressed SPD's request for documents related to Church & Dwight's February 2010 510(k) application. While the Court required Church & Dwight to produce all testing documents that related to the conclusion that Church & Dwight's First Response

¹Pursuant to the Medical Device Amendments of 1976, 21 U.S.C. § 360 *et seq.*, anyone seeking to market a Class II device is required to make a Premarket Notification to the FDA. These Premarket Notifications are commonly known as "510(k)" applications. *See* 21 U.S.C. § 360(k).

Early Result pregnancy test is 99% accurate on the day of EMP, including the test data submitted by Church & Dwight to the FDA, the Court did not require Church & Dwight to produce the then pending 510(k) or correspondence between Church & Dwight and the FDA regarding same. (*See* 11/29/10 Letter Order at 3; Docket Entry No. 172). In so doing, the Court noted “that Church & Dwight’s February 2010 510(k) involve[d] an advertising claim that Church & Dwight [wa]s not currently making and that SPD [wa]s not challenging.” (*Id.*) The Court additionally found that:

While the Court believes that the testing information related to that advertising claim falls within the broad scope of discovery permitted in Federal Court, it also finds that the FDA’s non-final reactions to same do not. *See* FED.R.CIV.P. 26(b). Further, the Court finds that Church & Dwight did not open the door to the wholesale discovery of all documents concerning the February 2010 510(k) application by referring to same in its motion to dismiss in order to attempt to establish its primary jurisdiction defense.

(*Id.*)

At the time the Court entered the aforementioned Letter Order, It believed that the FDA would make a determination on Church & Dwight’s 510(k) application. The Court did not anticipate the contingency under which the 510(k) application would be withdrawn. Church & Dwight’s withdrawal of the 510(k) application, however, has no effect on the Court’s substantive rulings that (1) the FDA’s non-final reactions to Church & Dwight’s proposed advertising claim are not relevant and (2) Church & Dwight did not open the door to wholesale discovery of all documents concerning its February 2010 510(k) application by referring to the application in its motion to dismiss in order to attempt to establish a primary jurisdiction defense. Indeed, the Court’s analysis in this regard remains unchanged. In light of the fact that there has been no final FDA determination regarding Church & Dwight’s February 2010 510(k) application, the Court’s earlier decision holds: the FDA’s

non-final reactions to Church & Dwight's proposed advertising claims are not relevant. This is true despite the fact that Church & Dwight's withdrawal of its February 2010 510(k) means that there may never be a final FDA decision regarding same. As a result, SPD's request for documents related to Church & Dwight's February 2010 510(k) application, including correspondence between Church & Dwight and the FDA regarding same, is DENIED.

IT IS SO ORDERED.

s/ Tonianne J. Bongiovanni
TONIANNE J. BONGIOVANNI
United States Magistrate Judge